ST. JUDE MEDICAL
MORE CONTROL LESS RISK

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Corporate ID no: 556335-9446

Attachment 4

MAR 2 8 2013

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements in 21 CFR §807.92

Submitted by:	St. Jude Medical Systems AB Palmbladsgatan 10, Box 6350 SE-751 35 Uppsala, Sweden Phone:+46 18 161000
Contact Person:	Anna-Lisa Tiensuu
Date Prepared:	December 18, 2012
Proprietary Name:	QUANTIEN™ Measurement System
Common Name:	QUANTIEN
Classification Name:	§870.1425, Programmable diagnostic computer
Predicate Device:	RadiAnalyzer® Xpress K092105

Description of the Device:
QUANTIEN Measurement System is a diagnostic computer designed to record, compute, display and store data from PressureWire™ guidewire (K113584, K080813, K062769) and other external transducers. The information is displayed as graphs as well as numerical values on the screen. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR) and data from ECG.

Information on screen can also be transferred to an external hemodynamic recording system or to an external video monitor. Recorded procedures can be viewed on a PC for review and analysis with application specific viewing software installed, such as RadiView™ software.

Additional functions allow for import of a patient work list from the hospital DICOM system, export recorded measurement data to DICOM or to an external server location or save it to a USB memory stick.

Intended Use of the Device:
QUANTIEN Measurement System is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from one or more electrodes, transducers or measuring devices.

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QUANTIEN system is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters with PressureWire.

Technical Characteristics:
The reason for the device modification is that some components in RadiAnalyzer Xpress have reached end of life because of technological advancements (e.g., design of electronic components). In addition, user/market feedback has been addressed to improve the usability of the device in the intended environment (catheterization laboratories), and data connectivity (e.g. DICOM, USB, network).

The subject device, Quantien Measurement System, meets the design inputs and raises no new safety or efficacy concerns.

Quantien Measurement System is determined to be substantially equivalent to the marketed predicate device, RadiAnalyzer Xpress (K092105). The substantial equivalence is based on the similarities in intended use, operational characteristic and the same fundamental design and technology as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 28, 2013

St. Jude Medical Systems AB
c/o Ms. Anna-Lisa Tiensuu
Palmbladsgatan 10
Box 6350
Uppsala SE-751 35
Sweden

Re: K123984
Trade/Device Name: QUANTIEN™ Measurement System
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK, DSK
Dated: February 28, 2013
Received: March 1, 2013

Dear Ms. Tiensuu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indication for Use Statement

510(k) Number: _____

Device Name: QUANTIEN™ Measurement System

Indications for Use: QUANTIEN Measurement System is indicated to provide hemodynamic information for use in the diagnosis and treatment of coronary or peripheral artery disease.

QUANTIEN Measurement System is intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices.

Prescription Use ____X_____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Owen P. Faris -S
2013.03.28
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